

REMARKS

I. PRELIMINARY REMARKS

No claims have been amended, added or canceled. Claims 8-14 and 16-25 remain in the application. Reexamination and reconsideration of the application are respectfully requested.

II. PRIOR ART REJECTIONS

Claims 8-12 and 16-20 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 4,940,062 to Hampton ("the Hampton patent"). Claims 13-14 and 21-25 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Hampton patent and U.S. Patent No. 4,848,352 to Pohndorf ("the Pohndorf patent").¹ The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

III. DISCUSSION CONCERNING CLAIMS 8-12 AND 16-20

A. The Claimed Combinations

Independent claim 8 calls for a combination of elements comprising "***a main body portion*** defining a proximal end and a distal end and ***including a malleable portion*** fixedly positioned between the proximal and distal ends," "***a deflectable***

¹ Applicant notes that the statement of rejection on page 2 of the Office Action did not mention claims 18-20, that the statement of rejection on page 4 of the Office Action did not mention claims 21-25, that the first line on page 6 refers to claim 22 instead of claim 25, and that the present remarks are based on applicant's assumptions concerning the rejections. Applicant hereby requests that the Examiner clarify the rejections in the next Action in order to avoid the delays associated with the Board remanding the application back to the Examiner for clarification of the record after the appeal process has begun.

portion extending distally from the distal end of the main body portion and **deflectable relative to** the main body portion,” “a steering mechanism, operably connected to the deflectable portion, that bends the deflectable portion relative to the main body portion” and “at least one operative element carried by the deflectable portion.” The respective combinations defined by claims 9-12 and 16-20 include, *inter alia*, the elements recited in claim 8.

B. The Hampton Patent

The Hampton patent is directed to a guide member with a deflectable tip. Referring to Figure 1, the Hampton guide member includes a tubular element 12, a helical coil 13 extending distally from the tubular element, and a core element 11 that extends through the tubular element and helical coil, and is secured to the distal end of the helical coil by a plug 22. The helical coil includes an expanded section 16 with a flat reference element 18 mounted therein. So configured, movement of the core element 11 causes the expanded section 16 and reference element 18 to deflect in the manner indicated by arrow 40. [Column 4, lines 24-46.] Turning to Figure 5, the Hampton patent also indicates that the guide member illustrated in Figure 1 may be incorporated into a dilation catheter with a dilation balloon 47. The Hampton patent also discloses that the flattened section 24 of the core 11 may be manually bent. [Figure 12; column 5, line 64 to column 6, line 12.]

C. Claim Interpretation Issues Raised By the Office Action

Referring to Figure 1 of the Hampton patent, which is reproduced on the following page, the Office Action has apparently taken the position that element 10 corresponds to the claimed “main body portion,” that element 13 corresponds to the claimed “deflectable portion,” that elements 14, 15, 18 and 24 correspond to the claimed “steering mechanism” and that elements 17, 18 and 47 correspond to the claimed “operative element.” [Office Action at pages 2-3.] In other words, the Office Action has

apparently taken the position that the *entire* Hampton guidewire 10 corresponds to the claimed "main body portion" and that the helical coil 13 corresponds to the claimed "deflectable portion." Applicant respectfully submits that such an interpretation is utterly unreasonable because independent claim 8 requires that the "deflectable portion **[extend] distally from** the distal end of the main body portion and **[be] deflectable relative to** the main body portion." The purported "deflectable portion" (i.e. the helical coil 13) simply cannot extend distally from, and deflect relative to, the purported "main body portion" (i.e. the entire guidewire 10) when the purported "deflectable portion" (i.e. the helical coil 13) is part of the purported "main body portion" (i.e. the entire guidewire 10).

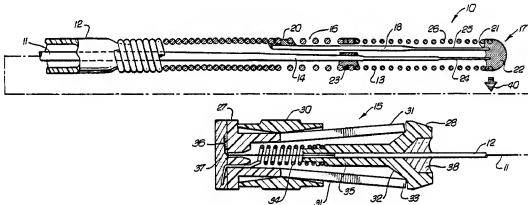


Figure 1 of the Hampton Patent

As the rejection of claims 8-12 and 16-20 under 35 U.S.C. § 102 is based on an unreasonable interpretation of the claims, applicant respectfully submits that it is improper and should be withdrawn.

It should also be noted that the Office Action did not identify which element in the Hampton device purportedly corresponds to the claimed "malleable portion" of the "main body portion." Instead, the Office Action referred to column 3, lines 11-39 of the Hampton patent. This portion of the Hampton patent makes reference to elements 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 21, 22 and 23. ***In order to clarify the issues for appeal, applicant hereby requests that the next action identify, by reference numeral(s), which portion of the Hampton device corresponds to the claimed "malleable portion."***

D. Comparison of Claims 8-12 and 16-20 to the Disclosure of the Hampton Patent

Applicant also notes for the record that the Hampton patent fails to teach or suggest a variety of aspects of properly interpreted independent claim 8. Assuming *arguendo* that the tubular element 12 corresponds to the claimed "main body portion," that the helical coil 13, which deflects relative to the tubular element 12, corresponds to the claimed "deflectable portion," and that the dilation balloon 47 corresponds to the claimed "operative element," the purported "operative element," i.e. the dilation balloon 47, is not carried by the purported "deflectable portion," i.e. the helical coil 13. The distal tip 17 and the reference element 18, which were mentioned in the Office Action, are not "operative elements."

Additionally, assuming *arguendo* that the flattened section 24 of the Hampton core element in Figure 12 corresponds to the claimed "malleable portion," the flattened section 24 is not located between the proximal and distal ends of the "main body portion," i.e. the tubular element 12. Alternatively, assuming *arguendo* that the entire core element 11 corresponds to the claimed "malleable portion," the core element 11 is not "fixedly positioned between the proximal and distal ends" of the "main body portion," i.e. the tubular element 12. Instead, the core element 11 is free to move proximally and distally relative to the tubular element 12.

As the Hampton patent fails to teach or suggest each and every element of the combination recited in independent claim 8, applicant respectfully submits that the rejection of claims 8-12 and 16-20 under 35 U.S.C. § 102 should be withdrawn.

IV. DISCUSSION CONCERNING CLAIMS 13 AND 14

With respect to the rejection under 35 U.S.C. § 103, applicant respectfully submits that the Pohndorf patent fails to remedy the above-identified deficiencies in the Hampton patent. As such, claims 13 and 14 are patentable for at least the same reasons as independent claim 8. Applicant also notes for the record that the Pohndorf

"pacing lead" patent would not have suggested adding electrodes to a guiding member such as that disclosed in the Hampton patent. The rejection of claims 13 and 14 under 35 U.S.C. § 103 should, therefore, also be withdrawn.

V. DISCUSSION CONCERNING CLAIMS 21-25

A. The Claimed Combinations

Independent claim 21 calls for a combination of elements comprising "a tubular catheter body including a tubular malleable portion and a distal portion that is distal of the tubular malleable portion," "a steering spring mounted within the tubular distal portion," "at least one **steering wire** that **extends through** the tubular malleable portion and is **connected to** the steering spring" and "at least one electrode carried by the distal portion of the tubular catheter body." The respective combinations defined by claims 22-25 include, *inter alia*, the elements recited in claim 21.

B. The Cited References

The Hampton patent is directed to a guide member with a deflectable tip. Referring to Figure 1, the Hampton guide member includes a tubular element 12, a helical coil 13 extending distally from the tubular element, and a core element 11 that extends through the tubular element and helical coil, and is secured to the distal end of the helical coil by a plug 22. The helical coil includes an expanded section 16 with a flat reference element 18 mounted therein. So configured, movement of the core element 11 causes the expanded section 16 and reference element 18 to deflect in the manner indicated by arrow 40. [Column 4, lines 24-46.] Turning to Figure 5, the Hampton patent also indicates that the guide member illustrated in Figure 1 may be incorporated into a dilation catheter with a dilation balloon 47. The Hampton patent also discloses that the flattened section 24 of the core 11 may be manually bent. [Figure 12; column 5, line 64 to column 6, line 12.]

The Pohndorf patent has been cited for its purported teachings concerning electrodes.

C. Discussion

The Office Action has taken the position that the entire Hampton guidewire 10 corresponds to the claimed "tubular catheter body," that the coil 13 corresponds to the claimed "tubular malleable portion" of the "tubular catheter body," and that two separate elements, i.e. the tapered portion 14 of the core element 11 **and** the reference element 18, correspond to the claimed "steering wire." [Office Action at page 5.] Applicant respectfully submits that there are a variety of errors associated with the positions taken in the Office Action.

For example, the claimed "**steering wire ... extends through** the tubular malleable portion and is **connected to** the steering spring." The first part of the purported Hampton two-part "steering wire," i.e. the core element tapered portion 14, is connected to the coil 13 (at location 23) and to the plug 22. The Office Action has, however, taken the position that the coil 13 corresponds to the claimed "tubular malleable portion" through which the "steering wire" extends, not to the claimed "steering spring," while the plug 22 is certainly not a "steering spring." The second part of the purported Hampton two-part "steering wire," i.e. the reference element 18, is only connected to the coil 13.² The Office Action has, however, taken the position that the coil 13 corresponds to the claimed "tubular malleable portion" through which the "steering wire" extends, not to the claimed "steering spring." As such, based on the claim interpretation proposed in the Office Action, there simply is no "**steering wire that extends through** the tubular malleable portion and is **connected to** the steering spring."

² It should also be noted for the sake of completeness that there is no reasonable interpretation of "steering wire" that would read on the Hampton reference element 18.

Another error relates to the fact that independent claim 21 calls for a “**tubular catheter body including** a distal portion that is distal of the tubular malleable portion.” The Office Action has taken the position that the Hampton coil 13 corresponds to the claimed “tubular malleable portion” of the “tubular catheter body.” In contrast to the claimed combination, however, there simply is no “distal portion [of a tubular catheter body] that is distal of” the coil 13. The only thing distal of the coil 13 is the plug 22 and, while the plug 22 is portion of the overall device, it is certainly not a portion of a “tubular catheter body.”

The Pohndorf patent, which is directed to a pacing lead, fails to remedy the above-identified deficiencies in the Hampton patent. In addition, there is nothing in the Pohndorf “pacing lead” patent itself that would not have suggested adding electrodes to a guiding member such as that disclosed in the Hampton patent. Applicant also respectfully notes that merely asserting that it would have been obvious to add electrodes to the Hampton device is insufficient to establish a *prima facie* case of obviousness under 35 U.S.C. § 103. *See KSR International C. v. Teleflex Inc.*, 82 USPQ 2d 1385, 1396 (S. Ct. 2007) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some **articulated reasoning with some rational underpinning** to support the legal conclusion of obviousness.”), *citations omitted, emphasis added*.

As the Hampton and Pohndorf patents fail to teach or suggest the combination of elements recited in independent claim 21, applicant respectfully submits that the rejection of claims 21-25 under 35 U.S.C. § 103 is improper and should be withdrawn.

Finally, the Office Action did not identify which elements in the Hampton device purportedly correspond to (1) the claimed “distal portion” of the “tubular catheter body” that is “distal of the tubular malleable portion” and (2) the claimed “steering spring” that is mounted within “the tubular distal portion” of the “tubular catheter body.” Although the Office Action made reference to Figure 6 with respect to the claimed “steering spring,” applicant notes that Figure 6 includes a plethora of elements, many of which are identically shown in Figure 1. ***In order to clarify the issues for appeal, applicant hereby requests that the next action identify, by reference numeral(s), which***

portion of the Hampton device corresponds to the claimed “distal portion” of the “tubular catheter body” that is “distal of the tubular malleable portion” and the claimed “steering spring.”

VI. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

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Date

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